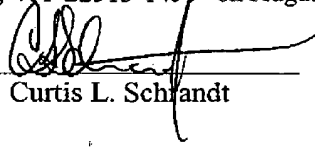


1743

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CENTRAL FAX CENTERCERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on August 12, 2004.


Curtis L. SchrandtAUG 12 2004
OFFICIALIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Vitolone et al.
U.S. Application No. : 10/031,423
U.S. Application Filed : 01/16/02
International Application No. : PCT/IB00/00966
International Filing Date : 14 July 2000 (14.07.00)
Title of Invention : PROCESS FOR THE QUANTITATIVE
DETERMINATION OF ALKALOIDS SUCH AS
COCAINE IN A SOLID SAMPLE AND REAGENT FOR
USE IN SUCH PROCESS
Examiner : L. A. Alexander
Art Unit : 1743

Commissioner for Patents
P.O. 1450
Alexandria, VA 22313-1450

MEMORANDUM

S I R:

This memorandum is in reference to the Office Action mailed July 19, 2004 in the above-identified application. This memorandum is not an amendment and is not to be entered in the application. This memorandum is for the Examiner's eyes only.

The Examiner points out in the Office action that the Office inadvertently did not consider the Preliminary Amendment filed on January 16, 2002 with the original application. However, it appears that the Office also did not consider the substitute claims that were submitted at the same time. The substitute claims (which were attached to and made a part of

the substitute specification) comprised Article 34 amendments made in the international application, i.e., PCT/IB00/00966.

The present Office Action appears to be applying the claims in the Preliminary Amendment to the original claims as published in the international application, rather than the substitute claims comprising the Article 34 amendments that should have been entered in the application at the initial filing.

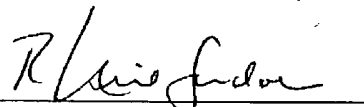
Enclosed herewith is a marked up version of the current state of the claims showing the amendments on the Preliminary Amendment as incorporated into the substitute claims that we filed with the original application. Also enclosed is a clean copy of the claims as they stand at this time.

Should the Examiner believe that direct contact with applicant's attorney would clear up the apparent confusion relating to the current state of the claims in the application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

By:



R. Neil Sudol
Reg. No. 31,669

Dated: August 12, 2004

714 Colorado Ave.
Bridgeport, Connecticut 06605-1601
203-366-3560

cc: Examiner L. A. Alexander @ 703-872-9306 (15 pp.)

*Not an amendment
Do not enter.*

**SUBSTITUTE CLAIMS (ARTICLE 34 AMENDED CLAIMS) FILED WITH
APPLICATION, AS FURTHER AMENDED BY PRELIMINARY AMENDMENT
DATED JANUARY 16, 2002 (ALSO FILED WITH APPLICATION)**

**CURRENT STATE OF CLAIMS IN THE APPLICATION PRIOR TO ANY OFFICE
ACTION (NON-MARKED UP VERSION)**

1. A screening-type process for the quantitative determination of cocaine and other alkaloids which are present in a solid sample which includes the steps of:

- a) preparing a solid sample in a finely divided or powdered form;
- b) selecting a liquid reagent providing constant concentration of hydroxyl groups suitable for extracting and transforming cocaine into benzoylecgonine and for extracting other similar substances;
- c) extracting cocaine and other similar substances contained in the sample and transforming the extracted cocaine into benzoylecgonine by maintaining the sample completely immersed in said liquid reagent at a temperature ranging from 10°C to 250°C for a period of time ranging from few seconds to 48 hours; and
- d) analysing the liquid separated from the solid sample to determine the concentration of benzoylecgonine contained in said liquid with respect to the cut-off limit using a conventional screening kit for the determination of the said substance in urine.

2. Process according to claim 1, wherein said solid sample is a sample of hair.

3. Process according to claim 1, wherein said temperature is ranging from 100°C to 150°C.

4. Process according to claim 1, wherein said period of time is ranging from 15 minutes to 24

hours.

5. Process according to claim 1, wherein said temperature is maintained at 100°C for 1 hour.
6. Process according to claim 1, wherein said liquid reagent is an ammonia buffer comprising 0.2 M $(\text{NH}_4)_2\text{HPO}_4$ with the addition of 5 ml of 25% NH_4OH to each liter thereof.
7. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of from 0.0001M to 5 M.
8. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.03M to 0.5 M.
9. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.04M to 0.33 M.
10. Process according to claim 1, wherein the analyzed samples are arranged in increasing order of concentration of cocaine or other alkaloids.
11. Process according to claim 1, wherein the samples are subjected to confirmation analyses with standard techniques such as GC or GC/MS.
12. Process according to claim 2, wherein each hair sample is made of about 50mg to 300 mg of

finely divided and/or powdered hair.

13. Process according to claim 1, wherein said liquid reagent is a solution comprising a solute selected among aluminum hydroxide, barium hydroxide octahydrate, benzyltriethylammonium hydroxide, benzyltrimethylammonium hydroxide, calcium hydroxide, phenylhydrargirium hydroxide, lithium hydroxide, lithium hydroxide monohydrate, magnesium hydroxide, potassium hydroxide, potassium hydroxyantimoniate, sodium hydroxide, sodium hydroxide monohydrate, strontium hydroxide octahydrate, tetramethylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, dissolved in a solvent selected among ethanol, methanol, water, monobasic ammonium phosphate, ammonium acetate, ammonium benzoate, ammonium bicarbonate, ammonium bichromate, ammonium bisulphate, ammonium bromide, ammonium carbamate, ammonium carbonate, ammonium citrate bibasic, ammonium chromate, ammonium iodide, molybdate, ammonium monovanadate, ammonium nitrate, ammonium oxalate monohydrate, ammonium persulphate, ammonium sulphate, ammonium sulphamate, ammonium sulphite, ammonium sulphide, ammonium tartrate, ammonium thiocyanate, ammonium thioglycolate, ammonium thiosulphate, ammonium chloride, sodium phosphate monobasic, sodium phosphate bibasic, potassium phosphate monobasic, potassium phosphate bibasic.

14. Diagnostic kit for carrying out the process according to claim 1, comprising a liquid reagent with constant concentration of hydroxyl groups suitable for extracting cocaine and other alkaloids and transforming cocaine into benzoylecgonine, and a conventional screening kit for the determination of said metabolite in urine samples.

not an Amendment
Do Not Enter

**SUBSTITUTE CLAIMS (ARTICLE 34 AMENDED CLAIMS) FILED WITH
APPLICATION, AS FURTHER AMENDED BY PRELIMINARY AMENDMENT
DATED JANUARY 16, 2002 (ALSO FILED WITH APPLICATION)**

**CURRENT STATE OF CLAIMS IN THE APPLICATION PRIOR TO ANY OFFICE
ACTION (MARKED UP VERSION)**

1. A screening-type process for the quantitative determination of cocaine and other alkaloids which are present in a solid sample which includes the steps of:
 - a) preparing a solid sample in a finely divided or powdered form;
 - b) selecting a liquid reagent providing constant concentration of hydroxyl groups suitable for extracting and transforming cocaine into benzoylecgonine and for extracting other similar substances;
 - c) extracting cocaine and other similar substances contained in the sample and transforming the extracted cocaine into benzoylecgonine by maintaining the sample completely immersed in said liquid reagent at a temperature ranging from 10°C to 250°C for a period of time ranging from few seconds to 48 hours; and
 - d) analysing the liquid separated from the solid sample to determine the concentration of benzoylecgonine contained in said liquid with respect to the cut-off limit using a conventional screening kit for the determination of the said substance in urine.
2. Process according to ~~claims~~ claim 1, wherein said solid sample is a sample of hair.
3. Process according to ~~claims~~ claim 1 and 2, wherein said temperature is ranging from 100°C to 150°C.

4. Process according to ~~claims~~ claim 1 ~~and 2~~, wherein said period of time is ranging from 15 minutes to 24 hours.
5. Process according to ~~any preceding claims~~ claim 1, wherein said temperature is maintained at 100°C for 1 hour.
6. Process according to claim 1, wherein said liquid reagent is an ammonia buffer comprising 0.2 M (NH₄)₂HPO₄ with the addition of 5 ml of 25% NH₄OH to each liter thereof.
7. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of from 0.0001M to 5 M.
8. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.03M to 0.5 M.
9. Process according to claim 6, wherein the concentration of hydroxyl groups in said ammonia buffer is in the range of 0.04M to 0.33 M.
10. Process according to ~~any preceding claims~~ claim 1, wherein the analyzed samples are arranged in increasing order of concentration of cocaine or other alkaloids.
11. Process according to ~~claim any preceding claims~~ claim 1, wherein the samples are subjected to confirmation analyses with standard techniques such as GC or GC/MS.

12. Process according to ~~any preceding claims~~ claim 2, wherein each hair sample is made of about 50mg to 300 mg of finely divided and/or powdered hair.
13. Process according to claim 1, wherein said liquid reagent is a solution comprising a solute selected among aluminum hydroxide, barium hydroxide octahydrate, benzyltriethylammonium hydroxide, benzyltrimethylammonium hydroxide, calcium hydroxide, phenylhydrargirium hydroxide, lithium hydroxide, lithium hydroxide monohydrate, magnesium hydroxide, potassium hydroxide, potassium hydroxyantimonate, sodium hydroxide, sodium hydroxide monohydrate, strontium hydroxide octahydrate, tetramethylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, tetrapropylammonium hydroxide, trimethylvinylammonium hydroxide, dissolved in a solvent selected among ethanol, methanol, water, monobasic ammonium phosphate, ammonium acetate, ammonium benzoate, ammonium bicarbonate, ammonium bichromate, ammonium bisulphate, ammonium bromide, ammonium carbamate, ammonium carbonate, ammonium citrate bibasic, ammonium chromate, ammonium iodide, molybdate, ammonium monovanadate, ammonium nitrate, ammonium oxalate monohydrate, ammonium persulphate, ammonium sulphate, ammonium sulphamate, ammonium sulphite, ammonium sulphide, ammonium tartrate, ammonium thiocyanate, ammonium thioglycolate, ammonium thiosulphate, ammonium chloride, sodium phosphate monobasic, sodium phosphate bibasic, potassium phosphate monobasic, potassium phosphate bibasic.
14. Diagnostic kit for the carrying out of the process according to ~~any claims 1 to 13~~ claim 1, comprising a liquid reagent with constant concentration of hydroxyl groups suitable for

extracting cocaine and other alkaloids and transforming cocaine into benzoylecgonine, and a conventional screening kit for the determination of said metabolite in urine samples.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,423	01/16/2002	Vitenczo Vitolone	M38-025	6771

7590

07/19/2004

R. Neil Sudol
Coleman Sudol Sapone
714 Colorado Avenue
Bridgeport, CT 06605-1601

EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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JUL 21 2004

COLEMAN SUDOL SAPONE, P.C

Office Action Summary

Application No.

10/031,423

Applicant(s)

VITOLONE ET AL.

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 C.F.R. 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the 6/30/04 telephone interview.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-5, 11-15 and 17 is/are rejected.
 7) ☒ Claim(s) 6-10 and 16 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☒ Interview Summary (PTO-413)
 Paper No(s)/Mail Date 6/30/04.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____

Application/Control Number: 10/031,423
Art Unit: 1743

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The 6/30/04 telephone interview between Mr. Coleman and Ms. Warden, who was acting in the absence of the Examiner, concluded the Office had inadvertently not considered a 1/16/02 preliminary amendment before issuing the 4/1/04 non-final Office action. The Office regrets any inconvenience this may have caused Applicant and will issue a new non-final Office action considering the 1/16/02 preliminary amendment.

Claims 6-10 and 16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 6-10 and 16 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 11-15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite what is intended by a "conventional kit for the determination of ... " and "... using a kit of reagents ... ". The method of use of these kits is not defined.

Claim 1 is further vague and indefinite what is intended by "... constant concentration of hydroxyl groups ...". Generally, a solution would be expected to meet this limitation. For the purposes of examination, it will be assumed Applicant is claiming

Application/Control Number: 10/031,423
Art Unit: 1743

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a solution containing hydroxyl groups. The claim is also vague and indefinite what time is intended by "a few seconds".

Claim 17 does not properly further limit independent claim 12. Claim 17 is directed to a "diagnostic kit" which does not further limit the subject matter of claim 12 that is directed to a process.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 11-15 and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson et al. (USP 5,910,419).

Johnson et al. teach a method of testing hair samples for cocaine use. Column 2 lines 53 through column 6 teach collection of a hair sample and immersing the sample

Application/Control Number: 10/031,423
Art Unit: 1743


Page 4

in a solution containing hydroxyl groups. Specifically, column 3 line 3 teaches the claimed reagent Na_2HPO_4 . Column 4 lines 15+ teach sample extraction conditions of 70°C-75°C for 2 hours that meet the claimed range of 10-250°C for from a few seconds to 48 hours. Column 5 lines 66+ teach addition of 0.1%(v/v) ammonium hydroxide to the buffer which has been read on the claimed 5ml of 25% ammonium hydroxide (e.g. the reference teaches the approximated equivalent of 1ml/liter of 100% ammonium hydroxide whereas the claimed is 5ml of 25% ammonium hydroxide).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lyle A Alexander
Primary Examiner
Art Unit 1743

Interview Summary	Application No.	Applicant(s)	
	10/031,423	VITOLONE ET AL.	
	Examiner	Art Unit	
	Jill A. Warden	1743	

All participants (applicant, applicant's representative, PTO personnel):

(1) Jill A. Warden (3) _____

(2) Henry Coleman (4) _____

Date of Interview: 30 June 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal (copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: those in the preliminary amendment.

Identification of prior art discussed: N/A.


Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's representative called to inform us that the preliminary amendment had not been considered and asked if he needed to respond to the Office action. I indicated that this interview was sufficient response as the examiner would issue a supplemental Office action considering the preliminary amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required